

Amendment Under 37 C.F.R. § 1.111  
Serial No. 09/674,643  
Our Ref: Q61622

### **REMARKS**

Claims 1-3 and 15-36 are all the claims pending in the application. By way of this Amendment, Applicant has amended 15, 16, 19, 23, 24, 25, and 31.

Claims 23-25, 31, and 15-22 have been rejected under § 112 (second paragraph) as being indefinite. Applicant thanks the Examiner for carefully reviewing the claims and for indicating those portions of the claims which are deemed to be indefinite. Applicant has amended the claims with the Examiner's comments in mind. Thus, it is submitted that the claims, as amended, comply with the specificity requirements of § 112.

Claims 1, 3, 26-29, 30-32 and 36 have been rejected under § 102(b) as being anticipated by Dombrowski, et al. (U.S. Patent No. 4,790,828). In addition, claims 15-22 have been rejected under § 103 as being unpatentable over Wilkes, et al. (U.S. Patent No. 5,743,888). Further, claims 2, 23-25 have been rejected under § 103 as being unpatentable over Dombrowski, et al. in view of Cameron (U.S. Patent No. 5,197,954). Finally, claims 33-35 have been rejected under § 103 as being unpatentable over Dombrowski, et al. and further in view of Schlesinger (U.S. Patent No. 4,283,493). For the following reasons, Applicant respectfully traverses these rejections.

Of the claims that are pending, Applicant notes that only claims 1 and 15 are in independent form. Each of these claims recite the manner in which the resilient return hinge 19 is located between the rigid portion or leg 13 and the sleeve 10, with a neutral position (an equilibrium) so that the leg 13 forms an angle  $\alpha$  with respect to the axis 2, as illustrated in Figure

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1 of the subject application. Applicant respectfully submits that none of the references relied upon by the Examiner teaches or suggests this feature of the invention.

In more detail, Applicant submits that there are significant differences between the device according to Dombrowski. Those differences include the following:

- according to Dombrowski,: the flexible shoulder 34 (or resilient return hinge) is located between the two rigid portions 56 and 58 at the midpoint 54, whereas:
- according to the invention recited in independent claims 1 and 15: the resilient return hinge 19 is located between the rigid portion or leg 13 and the sleeve 10, with a neutral position (or of equilibrium) so that the leg 13 makes with the axis 2 an angle  $\alpha$  not nil. (well illustrated in Figure ).

This structural difference makes the device, according to the invention, have three distinct positions: two positions of equilibrium I and II, and a position of blocking III, which correspond respectively to a first position of protection of the sharp end of the needle, a second position allowing the use of the needle and a third position of blocking for preventing a new use of the needle.

These three positions are illustrated on Figure 1 of the subject application.

In contrast, the device in Dombrowski, presents only one position of equilibrium (Figure 1) allowing the use of the needle and a position of blocking for preventing a new use of the needle (Figure 3).

The function of protecting the sharp end of the needle according to the first position I of the device of the invention is not possible with the device of Dombrowski, and this is why the Dombrowski device requires the use of a needle cover (referenced 30).

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In view of the foregoing, Applicant respectfully submits that claim 1 patentably distinguishes over Dombrowski. Indeed, a careful review of the Examiner's rejection, shows that the Examiner has failed to even address this important feature discussed above, which is recited in claim 1.

As noted above, claim 15 has been rejected under § 102(b) as being anticipated by Wilkes et al. Although Applicant does not concede that this rejection is proper, to advance prosecution, Applicant amended claim 15 to include the important feature discussed above regarding the resilient return hinge. Thus, Applicant submits that claim 15, and its dependent claims, patentably distinguish over the cited art, including Wilkes, et al., for the reasons discussed above.

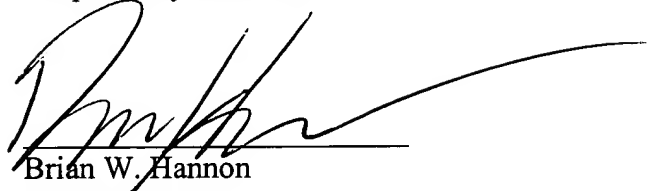
The remaining references relied upon by the Examiner in rejecting the various dependent claims (i.e., Cameron and Schlesinger) do not compensate for the above deficiencies of Dombrowski and Wilkes, et al.

In view of the foregoing, it is respectfully submitted that the application is now in condition for allowance. It is therefore requested that the application be passed to issue at the earliest convenience. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Brian W. Hannon', written over a horizontal line.

Brian W. Hannon  
Registration No. 32,778

SUGHRUE MION, PLLC  
2100 Pennsylvania Avenue, N.W.  
Washington, D.C. 20037-3213  
Telephone: (202) 293-7060  
Facsimile: (202) 293-7860

Date: July 26, 2002

**APPENDIX**

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE CLAIMS:**

**The claims are amended as follows:**

Claim 15 (Twice Amended) A device for protecting and neutralizing a needle for medical use or the like the needle having a sharp end and a base end, the device comprising:

a sleeve having a through bore, said through bore having first and second outlets, said through bore being defined on a given axis and having a cross-section that is not less than that of the needle, the needle being suitable for sliding through said bore;

a base secured to the base end of the needle; and

resilient link means connecting the sleeve to the base, said resilient link means enabling the sleeve to slide along the needle, the needle passing through the bore of the sleeve via the first outlet thereof, said sleeve being suitable for taking up two extreme positions:

a first sleeve position in which the sleeve surrounds the sharp end of the needle, said sharp end being situated at a given distance from the second outlet of the through bore; and

a second sleeve position in which the face of the sleeve that includes the first outlet of the through bore is positioned adjacent to the base; said resilient link means comprising at least:

a first link having first and second ends, said link being of a length "L<sub>1</sub>" defined between said two ends;

first resilient return hinge means for connecting the first end of the first link to the sleeve, said first hinge means being organized so that said first link takes up a defined

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15-A

equilibrium position on a direction that makes an acute angle ( $\alpha$ ) with the axis of the through bore;

a first crank arm, said first crank arm being defined between first and second ends, said crank arm being of a length " $l_1$ " defined between its two ends the length " $l_1$ " of the first crank arm being no greater than the length " $L_1$ " of the first link; and

first means for mounting each of said first and second ends of the first crank arm to pivot freely respectively on the second end of the first link and on the base means,

wherein ~~that it~~ said device further comprises:

a first channel portion made in the sleeve and intersecting the through bore in ~~its~~ a portion lying between its second outlet and the sharp end of the needle when the sleeve is in ~~its~~ the first sleeve position;

a shutter slidably mounted in the first channel portion, said shutter being suitable for taking up a first shutter position and a second shutter position, the first shutter position being one in which it is not situated in the through bore, and

means for applying thrust on said shutter when the sleeve comes close to the base on passing from ~~its~~ the first shutter position to ~~its~~ the second shutter position.

Claim 16 (Twice Amended). - A device according to claim 15, wherein the means for applying thrust on said shutter when the sleeve comes close to the base on passing from ~~its~~ the first sleeve position to ~~its~~ the second sleeve position are constituted by:

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a second channel portion made in the sleeve in continuity with the first channel portion and opening out via an outlet orifice in the same face of the sleeve as has the first outlet of the through bore;

a flexible rod preformed into an arcuate bow shape and slidably mounted in said second channel portion in such a manner that a first end thereof is associated with the shutter, and a second end thereof emerges from the outlet orifice of the second channel portion by an amount that is not less than the distance the shutter needs to travel in order to pass from ~~its~~ the first shutter position to ~~its~~ the second shutter position; and

a release cavity adjacent the second channel portion and in communication with said second channel portion, the release cavity being designed so that, when the shutter is held in ~~its~~ the first shutter position, the flexible rod can deform in bending to penetrate laterally into said release cavity when the face of the sleeve having the first outlet of the through bore comes close to the base.

Claim 18 (Twice Amended). A device according to claim 17, wherein the means [(227)] for locking the position of the second end of the flexible rod when it is retracted into the second channel portion is constituted by at least one barb secured to the flexible rod and a housing complementary to the barb formed in ~~the~~ a wall of the second channel portion.

Claim 19 (Twice Amended). A device according to claim ~~15~~ 16, wherein the first channel portion has at least a first part and a second part formed on either side of the through

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bore, the first part of the first channel portion being in line with the second channel portion, the shutter being contained completely within said first part of the first channel portion when ~~it~~the shutter is in ~~its~~the first shutter position, and by the fact that the device further includes a substantially U-shaped fork secured to the shutter and having two limbs, the two limbs of the fork being spaced apart from each other by a distance of not less than the diameter of the needle, said fork being shaped in such a manner that when the shutter is in ~~its~~the first shutter position, the space defined between the two limbs thereof is situated on the axis of the through bore and the two limbs extend at least in part into the second part of the first channel portion.

Claim 23 (Twice Amended). A device according to claim 1, wherein the base means comprises two first and second rings, the first ring receiving the ~~low~~base end of the needle, and means for connecting said two rings between them by weak points.

Claim 24 (Twice Amended) A device according to claim 23, wherein ~~each of the two rings comprises an~~respectively include two opening openings, the two openings being realized to form, when the two rings are connected between them, ~~the~~a female part of a male-female jointing able to cooperate with the complementary male part constituted by an end-part of a syringe, the total depth of these two openings, when the two rings are connected between them, being lower than the height of the end-part of the syringe.



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Claim 25 (Twice Amended). A device according to claim 23, further including a not-withdrawal ring located on ~~the~~a wall of said second ring.

Claim 31 (Amended). A device according to claim 1, wherein the length "L1" of the link and the length "I1" of the crank arm are determined in such a manner than the sum  $L1+I1$  and the sum  $L1+I1+M$ , where "M" represents the length of the sleeve, bracket the length "A" of the needle to be protected as measured between ~~its~~the sharp end and ~~its~~the base end.